DEPARTMENT OF HEALTH AND HUMAN SERVICES

Southwest Region

Food and Drug Administration
Denver District Office
Bldg. 20-Denver Federal Center
P.O. Box 25087
6th Avenue & Kipling Street
Denver, Colorado 80225-0087

Telephone: 303-236-3000

July 21, 2006

Warning Letter

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Mr. Larry Graziani
Betterthanair, LLC
P.O. Box 2488
35715 U.S. Highway 40, Suite D 103
Evergreen, CO 80437

Ref # DEN-06-21

Dear Mr. Graziani:

This letter concerns your firm's marketing of the "BetterThanAir™ oxygen enriched products" on your website, www.betterthanair.com. According to information on your website, the "BetterThanAir™ oxygen enriched products" referred to as: "Oxygen Kit," "O_Pur/BO-8L," "BlueAir," "PO24U Personal Oxygen System," "PO24U Refill," "'O'" 2 Go!," "BlueAir 2L," "Oxycan," "Oxygen Shot," "3rd Lung Kit," "BetterThanAir Emergency Oxygen M6 Travel Unit," "BetterThanAir Emergency Oxygen M9 Travel Unit," "Hangover Air," and "O_Pur/Eucalyptus," are intended to prevent, treat, or cure disease conditions or to affect the structure or any function of the body. The statements on your website that document these intended uses include, but are not limited to, the following:

-"AIDS
-Lung Cancer
-Chronic Mountain Sickness
-High Altitude Sickness (HAPE)
-Interstitial Lung Disease
-Cystic Fibrosis
-Sequelae Tuberculosis
-Bronchiectasis
-Kyphoscoliosis
-Neuromuscular Diseases
-Sleep Apnea Syndromes

-Primary Hypoventilation Syndromes
-Pulmonary Hypertension"

"Oxygen deprivation can, and is believed by the Medical Society to cause life-threatening diseases such as cancer."

"Today's breathable air is less than 21% oxygen. At one time our breathable air contained more than 50% oxygen. [The] cost is evident in the number of cases of cancer, AIDS, Heart Attacks and other illnesses that cripple and kill our bodies."

"Ideal applications for HangOverAir include: HangOvers and hangover symptoms associated with alcohol consumption."

"Certain health specialists say oxygen therapy is now a critical adjunct treatment for cancer, AIDS, diabetes, stroke, depression, chronic fatigue, lupus and fibromyalgia."

"BetterThanAir™ oxygen enriched products" are drugs, as defined by Section 201(g)(1) of the Federal Food, Drug, and Cosmetic Act (Act), [21 U.S.C. § 321(g)(1)], because they are intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease and to affect the structure or function of the body.

Moreover, these products are new drugs, as defined by section 201(p) of the Act, [21 U.S.C. § 321(p)], because they are not generally recognized as safe and effective for their labeled uses. Under sections 301(d) and 505(a) of the Act, [21 U.S.C. §§ 331(d) and 355(a)], a new drug may not be introduced or delivered for introduction into interstate commerce unless an FDA-approved application is in effect for it. Your sale of "BetterThanAir™ oxygen enriched products" without such approved applications violates these provisions of the Act.

Further, these oxygen products are also prescription drugs within the meaning of section 503(b)(1) of the Act, [21 U.S.C. § 353(b)(1)], because they are not safe for use except under the supervision of a practitioner licensed by law to administer such drugs. The "BetterThanAir™ oxygen enriched products" are misbranded within the meaning of section 503(b)(1) and 503(b)(4) of the Act, [21 U.S.C. §§ 353(b)(1) and 353(b)(4)] because they are marketed without a prescription and they lack the statement, "Rx only." The inclusion of the disclaimer, "Not for medical and prescription use," on the product's label does not remove the product from the prescription dispensing requirement of section 503(b)(2) of the Act [21 U.S.C. § 353(b)(2)].

Furthermore, because these products are offered for use for conditions that are not amenable to self-diagnosis and treatment by individuals who are not medical practitioners, adequate directions cannot be written so that a layperson can use these products safely for their intended uses. Thus, the "BetterThanAir™ oxygen enriched products" labeling fails to bear adequate directions for their intended uses, causing them to be misbranded under Section 502(f)(1) of the Act, [21 U.S.C. § 352(f)(1)]. These products are not exempt from the adequate directions for use requirement because they do not meet the conditions set forth in 21 CFR § 201.100.

Furthermore, these products are misbranded under section 502(o) of the Act, [21 U.S.C. § 352(o)] because the "BetterThanAir™ oxygen enriched products," are not listed as required by Section 510(i)(1) and (j)(1) of the Act [21 U.S.C. §§ 360(i)(l) and (j)(1)].

"BetterThanAir™ oxygen enriched products" are also subject to the Current Good Manufacturing Practice (CGMP) regulations at 21 CFR Parts 210 and 211. They may be considered adulterated under section 501(a)(2)(B) of the Act, [21 U.S.C. § 351(a)(2)(B)], if the methods used in, or the facilities or controls used during the product's manufacture, processing, packing, or holding do not conform to, or are not operated or administered in conformity with CGMP.

The above violations are not intended to be an all-inclusive list of deficiencies. It is your responsibility to ensure that the drug products that you manufacture, or distribute, meet all of the requirements of the Act and its implementing regulations. Federal agencies are advised of the issuance of all warning letters about drugs and devices so that they may take this information into account when considering the award of contracts.

You must immediately correct these violations. If you do not immediately correct them, you may be subject to FDA enforcement action without further notice. The Act provides for seizure of illegal products and for an injunctive relief against the manufacturers and distributors of illegal products. You must notify FDA in writing within 15 working days of receipt of this letter as to the steps that you have taken to correct the above-listed violations of the Act and its implementing regulations, and the steps taken to assure that similar violations will not recur. If corrective action cannot be completed within 15 working days, state the reason for the delay and the time within which the corrections will be made. Further, if your firm does not manufacture the products identified above, your reply should include the name and address of the manufacturer. If the firm from which you receive the product is not the manufacturer, please include the name of your supplier in addition to the manufacturing firm.

Your response should be directed to: Food and Drug Administration, Denver District, P. O. Box 25087, Denver, CO 80225-0087, Attention: William H. Sherer, Compliance Officer. If you have any questions, please contact Mr. Sherer at (303) 236-3051.

Sincerely yours,

B. Belinda Collins
District Director